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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/557,749	10/30/2006	Lee David Proctor	WPTL0104PUSA	2272

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EXAMINER

FORREST, MICHAEL

ART UNIT	PAPER NUMBER
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1793

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/557,749		PROCTOR ET AL.	
	Examiner		Art Unit	
	MICHAEL FORREST		1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☒ Claim(s) 3 and 10 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/18/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

Claim 3 is objected to because of the following informalities: p-ketoester appears to be a typographical error for β -ketoester based on the supporting information in the specification. Appropriate correction is required. For purposes of examination, p-ketoester is treated as β -ketoester further in the action.

Claim 10 is objected to because of the following informalities: P-ketoester appears to be a typographical error for β -ketoester based on the supporting information in the specification. Appropriate correction is required. For purposes of examination, P-ketoester is treated as β -ketoester further in the action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 provides for the use of a buffering compound or composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 15 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-3, 6-10, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al(US Patent 5,596,113) and further in view of Takaya et al(US Patent 5,412,109).

Douglas teaches a catalyst composition for asymmetric hydrogenation, the catalyst comprising:

- (1) a catalyst requiring trace amounts of strong acid to activate the reaction at low temperature;
- (2) a strong acid; and
- (3) an alcohol (see Col 1, Lines 58 to 67).

Douglas does not teach a catalyst composition further comprising a buffer solution capable of forming acetals, ketals, hemi-acetals, or hemi-ketals.

Takaya teaches a catalyst composition for asymmetric hydrogenation comprising a mixture of an aprotic solvent including acetone and other ketones, and a protic solvent including alcohols (see Col 9, Line 67 to Col 10, Line 16). Takaya further teaches that when a mixed solvent is used, deactivation of catalyst activity formed during reaction can be prevented and the reaction time can be shortened (see Col 10, Lines 9 to 17). Takaya further discloses side reactions from the solvent mixture with the presence of acids (See Col 10, Line 14-16). One potential side reaction is the synthesis of ketals from ketones and alcohols in the presence of acid.

It would have been obvious to one of ordinary skill in the art at the time of the invention to produce the catalyst composition as taught by Douglas with a mixed solvent of a ketone and alcohol (capable of synthesizing ketals in the presence of acid) as taught by Takaya to prevent deactivation of the catalyst and shorten the reaction time.

Regarding Claim 2, Douglas teaches a catalyst composition where the catalyst is a BINAP (see Col 1, Lines 58 to 67).

Regarding Claim 3, Douglas teaches a catalyst composition where the catalyst is effective for catalyzing asymmetric dehydrogenation of β -ketoesters (see Col 1, Lines 58 to 67).

Regarding Claim 6, Takaya teaches catalyst compositions comprising an aprotic solvent including acetone and a protic solution including methanol (see Col 9, Line 67 to Col 10, Line 16). It would have been obvious to one of ordinary skill in the art at the time of the invention to select those two solvents by routine experimentation since the genus is limited and a mixture is encouraged by the prior art.

Regarding Claim 7, Takaya teaches a catalyst where ketone and alcohol are the solvent for the asymmetric dehydrogenation reaction (see Col 9, Line 67 to Col 10, Line 16).

Regarding Claim 8, Douglas teaches a process for asymmetric hydrogenation comprising:

- (1) contacting β -ketoesters with
- (2) a catalyst requiring trace amounts of strong acid to activate the reaction at low temperature;
- (2) a strong acid;
- (3) an alcohol; and
- (4) in the presence of hydrogen (see Col 1, Lines 58 to 67)

Douglas does not teach a process for asymmetric hydrogenation further comprising a buffer solution capable of forming acetals, ketals, hemi-acetals, or hemi-ketals.

Takaya teaches a process for asymmetric hydrogenation where the solvent comprises a mixture of an aprotic solvent including acetone and other ketones, and a protic solvent including alcohols (see Col 9, Line 67 to Col 10, Line 16). Takaya further teaches that when a mixed solvent is used deactivation of catalyst activity formed during reaction can be prevented and the reaction time can be shortened (see Col 10, Lines 9 to 17). Takaya further discloses side reactions from the solvent mixture with the presence of acids (See Col 10, Line 14-16). One potential side reaction is the synthesis of ketals from ketones and alcohols in the presence of acid.

It would have been obvious to one of ordinary skill in the art at the time of the invention to perform the process for asymmetric dehydrogenation as taught by Douglas with a mixed

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solvent of a ketone and alcohol (capable of synthesizing ketals in the presence of acid) as taught by Takaya to prevent deactivation of the catalyst and shorten the reaction time.

Regarding Claim 9, Douglas teaches a process where the catalyst is a BINAP (see Col 1, Lines 58 to 67).

Regarding Claim 10, Douglas teaches a process where the catalyst is effective for catalyzing asymmetric dehydrogenation of β -ketoesters (see Col 1, Lines 58 to 67).

Regarding Claim 13, Takaya teaches process comprising an aprotic solvent including acetone and a protic solution including methanol (see Col 9, Line 67 to Col 10, Line 16). It would have been obvious to one of ordinary skill in the art at the time of the invention to select those two solvents by routine experimentation since the genus is limited and a mixture is encouraged by the prior art.

Regarding Claim 14, Takaya teaches a process where ketone and alcohol are the solvent for the asymmetric dehydrogenation reaction (see Col 9, Line 67 to Col 10, Line 16).

Regarding Claim 15, the claim is rejected for reasons as applied to Claim 8. Improving the enantiomeric excess of desired product is merely a statement of intended effect and is not further limiting to the structure of the catalytic composition.

Claims 4-5 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al(US Patent 5,596,113) in further view of Takaya et al(US Patent 5,412,109) as applied to claim 1 or 8 above, and further in view of Pavlov et al(Enantioselective hydrogenation of β -keto esters catalyst by chiral binaphthylbisphosphine ruthenium complexes, Russian Chemical Bulletin, Vol 49, No. 4, April, 2000, pp. 728-731).

Douglas and Takaya as applied to claim 1 teach a catalyst composition comprising a catalyst requiring trace amounts of strong acid, strong acid, and a solvent mixture of ketone and alcohol.

Douglas and Takaya do not teach a catalyst composition where the acidic material comprises a substrate suitable for asymmetric hydrogenation assisted by the catalyst.

Pavlov teaches a catalyst complex comprising a BINAP catalyst and a substrate consisting of ethyl-4-chloroacetoacetate without addition of HCl (see Page 728, Para 1 and 2, and Figure 1, substrate 4). Pavlov further teaches that the catalyst complex hydrogenated the substrate quantitatively and enantioselectively without the addition of HCl (see Page 728, Para 2). It would have been obvious to one of ordinary skill in the art at the time of the invention to produce the catalyst composition as taught by Douglas and Takaya with ethyl-4-chloroacetate to produce a hydrogenated product quantitatively and enantioselectively without additional acid.

Regarding Claims 11-12, Douglas and Takaya as applied to claim 8 teach a process comprising contacting a substrate with a catalyst composition comprising a catalyst requiring trace amounts of strong acid, strong acid, and a solvent mixture of ketone and alcohol, in the presence of hydrogen.

Douglas and Takaya do not teach a process where the acidic material comprises a substrate suitable for asymmetric hydrogenation assisted by the catalyst.

Pavlov teaches a process where a BINAP catalyst hydrogenates substrate consisting of ethyl-4-chloroacetoacetate without addition of HCl (see Page 728, Para 1 and 2, and Figure 1, substrate 4). Pavlov further teaches that the catalyst complex hydrogenated the substrate

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quantitatively and enantioselectively without the addition of HCl (see Page 728, Para 2). It would have been obvious to one of ordinary skill in the art at the time of the invention to perform the process as taught by Douglas and Takaya with ethyl-4-chloroacetate as the substrate to produce a hydrogenated product quantitatively and enantioselectively without additional acid.

Conclusion

Claims 1-15 are pending. Objections are made to Claims 3 and 10. Claims 1-15 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL FORREST whose telephone number is (571)270-5833. The examiner can normally be reached on Monday - Thursday, 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Curtis Mayes can be reached on (571)272-1234. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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12/04/2008

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